WSA 2004 Proposed Project

Project Name:	TES Follow-up Study (N01459)
Purpose:	Estimation of cigarette smoke exposure of participants in the TES who changed FTC tar delivery category using selected biomarkers of exposure and biologically effective dose. Evaluation of any change in smoking behavior (questionnaire and topography) associated with the change in FTC tar delivery category.

Reason for Doing this Work:

- ☒ Guidance
- ☐ Evaluation
- ☐ Product Design
- ☐ Short Term
- ☒ Long Term

Initiative and sub-initiative: (Check all areas that apply)

- ☐ Determinants of Exposure
  - ☐ Addiction
  - ☐ Ammonia
- ☒ Understanding Product Toxicity vs Product Design
  - ☒ Exposure
  - ☐ Carbon
  - ☐ Menthol
  - ☐ Low Tar
  - ☐ ETS
  - ☐ Specific Compounds
- ☐ Evaluation Framework Clinical
  - ☐ Cancer
  - ☐ COPD
  - ☐ CVD
  - ☐ Molecular Biology
  - ☐ All Disease
- ☐ Evaluation Framework Non-Clinical
  - ☐ Cancer
  - ☐ COPD
  - ☐ CVD
  - ☐ Molecular Biology
  - ☐ All Disease
- ☐ Broaden Flexibility after Clinical Studies
- ☐ Rapid Screening
- ☐ Knowledge Management
- ☐ Risk Assessment
- ☐ Communication
- ☐ Surveillance
- ☐ Smoking Conditions
- ☐ Improve Prep Subjectives
- ☐ Lit End Cigarette Reduced Exposure Design

Project Leader:	Jan Oey
Functional Area:	Clinical Evaluation
Prioritization:	☒ Critical ☐ Priority ☐ Secondary ☐ Low

Milestones:	**Target Start Date**	**Previous Completion Date**	**Target Completion Date:**
Study protocol and questionnaire completed	N/A	04/30/03	12/16/03
IRB Approval	N/A	06/30/03	12/22/03
Start of follow-up contact by the call center	N/A	08/30/03	01/01/04
Completion of follow-up contact	N/A	09/30/04	04/30/04
Collection of samples completed	N/A	10/31/04	11/31/04
Bio-analytical completed	N/A	12/31/04	01/31/05
Data analysis completed	N/A	04/30/05	05/31/05
Draft report	N/A	10/31/05	11/31/05
Final Report	N/A	12/31/05	01/31/06

Internal Resource Allocation (WSA, PMRL, PMI) (Man Hours)	**External Resource Allocation (other PMUSA, external vendors)** (Man Hours)
Jan Oey: ~~340~~ 100; Candace Adams: ~~170~~ 20; Bettie Nelson: ~~170~~ 50; Barb Zedler: ~~170~~ 100; Hans Roethig: ~~50~~ 20; Robin Kinser: ~~50~~ 0; Mohamadi Sarkar: ~~50~~ 0; Qiwei Liang: ~~25~~ 0; M.Unverdorben ~~25~~ 0	

TO BE FILLED OUT BY WSA MANAGEMENT

- ☐ Approved as Written
- ☐ Approved with Modifications
- ☐ Not Approved

Signature of Project Leader's Functional Director (Date)

PM3005219826

Source: https://www.industrydocuments.ucsf.edu/docs/fklj0001